Shropshire Community Health NHS Trust

NHS Telford and Wrekin Clinical Commissioning Group

Fluoxetine
Effective Shared Care Agreement
For the treatment of moderate to severe major depression in children and adolescents

Section 1: Shared Care arrangements and responsibilities

Section 1.1 Agreement to transfer of prescribing of Fluoxetine to GP

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details
Consultant:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient/Carer

Name:

Contact number:

Agreement to shared care, to be signed by GP and Consultant before prescribing is transferred to GP

Consultant Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient /Carer Signature: _____

Date: _____

Section 1.2: Shared Care responsibilities

This Effective Shared Care Agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist.
If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment
1. Discuss with the patient/carer options for treatment and the suitability of fluoxetine.
2. Discuss the potential benefits and side effects of treatment with the patient/carer:
3. Initiate fluoxetine treatment.
4. Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient./carer.
5. Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
6. Ensure this has been discussed with patient, and that patient has signed SCA form
7. Regular follow-up of patient (at least annually)
8. Communicate promptly with the GP when treatment is changed
9. Advise GP on dosage adjustment and when and how to stop treatment
10. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
11. Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner
1. Reply to the request for shared care as soon as practicable, and if required discuss shared care arrangements with patient/carer.
2. Prescribe fluoxetine at the dose recommended.
3. Arrange and record on-going monitoring as agreed with specialist:
4. Ensure no drug interactions with other medicines
5. Continued prescribing is appropriate for patients attending regular review
6. Report adverse events to the MHRA (via Yellow Card).

Responsibilities of the patient
1. To take the prescribed medication regularly unless advised by GP or specialist
2. To attend scheduled appointments with consultant and GP and for monitoring as detailed above
3. Report any adverse effects to the consultant or GP.
4. Share any concerns in relation to treatment.
6. Report to the consultant or GP if they do not have a clear understanding of the treatment

Section 2: General Information on fluoxetine

Background

NICE[1] recommend fluoxetine as a possible treatment in combination with a concurrent psychological therapy, if psychological therapy is declined, fluoxetine may still be given, but there must be regular monitoring and focus on adverse drug reactions.

Prescribing should only occur after assessment and diagnosis by a child and adolescent psychiatrist.

Licensed Indication

Children and Adolescents aged 8 years and above:

Moderate to severe major depressive episode, if depression is unresponsive to psychological therapy after 4-6 sessions. Antidepressant medication should be offered to a child or young person with moderate to severe depression only in combination with a concurrent psychological therapy.

Dosage and administration

Treatment should be initiated and monitored under specialist supervision. The starting dose is 10mg/day given as 2.5ml of the fluoxetine liquid formulation. Dose adjustments should be made carefully, on an individual basis, to maintain the patient at the lowest effective dose.

After one to two weeks, the dose may be increased to 20mg/day. Clinical trial experience with daily doses greater than 20mg is minimal. There is only limited data on treatment beyond 9 weeks.

Lower-weight children: Due to higher plasma levels in lower-weight children, the therapeutic effect may be achieved with lower doses (see section 5.2).

For paediatric patients who respond to treatment, the need for continued treatment after 6 months should be reviewed. If no clinical benefit is achieved within 9 weeks, treatment should be reconsidered.

Contraindications

Suicide-related behaviours (suicide attempt and suicidal thoughts) and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, only limited evidence is available concerning long-term effect on safety in children and adolescents, including effects on growth, sexual maturation and cognitive, emotional and behavioural developments.

Growth and pubertal development (height, weight, and TANNER staging) should be monitored during and after treatment with fluoxetine. If either is slowed, referral to a paediatrician should be considered.

In paediatric trials, mania and hypomania were commonly reported, therefore regular monitoring for the occurrence of mania/hypomania is recommended. Fluoxetine should be discontinued in any patient entering a manic phase.

Side effects

Rash and allergic reactions: Rash, anaphylactoid events and progressive systemic events, sometimes serious (involving skin, kidney, liver or lung), have been reported. Upon the appearance of rash or of other allergic phenomena for which an alternative aetiology cannot be identified, fluoxetine should be discontinued.

Seizures: Seizures are a potential risk with antidepressant drugs. Therefore, as with other antidepressants, fluoxetine should be introduced cautiously in patients who have a history of seizures. Treatment should be discontinued in any patient who develops seizures or where there is an increase in seizure frequency. Fluoxetine should be avoided in patients with unstable seizure disorders/epilepsy and patients with controlled epilepsy should be carefully monitored.

Mania: Antidepressants should be used with caution in patients with a history of mania/hypomania. As with all antidepressants, fluoxetine should be discontinued in any patient entering a manic phase.

Hepatic/Renal function*:* Fluoxetine is extensively metabolised by the liver and excreted by the kidneys.

Suicide/suicidal thoughts or clinical worsening*:* Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery. .

Akathisia/psychomotor restlessness: The use of fluoxetine has been associated with the development of akathisia, this is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.

Withdrawal symptoms seen on discontinuation of SSRI treatment*:* Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt.

Haemorrhage: There have been reports of cutaneous bleeding abnormalities, such as ecchymosis and purpura with SSRIs. Ecchymosis has been reported as an infrequent event during treatment with fluoxetine. Other haemorrhagic manifestations (e.g., gynaecological haemorrhages, gastro-intestinal bleedings and other cutaneous or mucous bleedings) have been reported rarely.

On rare occasions, development of a serotonin syndrome or neuroleptic malignant syndrome-like events have been reported in association with treatment of fluoxetine, particularly when given in combination with other serotonergic (among others, L-tryptophan) and/or neuroleptic drugs. As these syndromes may result in potentially life-threatening conditions, treatment with fluoxetine should be discontinued if such events (characterised by clusters of symptoms, such as hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes, including confusion, irritability, extreme agitation, progressing to delirium and coma) occur and supportive symptomatic treatment should be initiated.

Fluoxetine oral liquid contains sucrose*:* Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Drug Interactions[2]

NSAIDs- increased risk of bleeding.

MAOIs-avoid concomitant use, risk of severe toxicity.

Antiepileptics- may antagonise anticonvulsant effect and increase plasma concentrations of carbamazepine and phenytoin.

Antipsychotics-may increase plasma concentration of clozapine, haloperidol and risperidone.

Atomoxetine- possible increased risk of convulsions.

Tamoxifen- may inhibit metabolism to active metabolite.

Serotonergic drugs (tramadol, triptans) - may increase risk of serotonin syndrome.

There are numerous drug interactions and the Summary of Product Characteristics (www.medicines.org.uk) should be consulted both before treatment and when new drugs are introduced.

Monitoring

Only limited evidence is available concerning long-term effect on safety in children and adolescents, therefore there is a need for regular monitoring of the effects of fluoxetine on growth, sexual maturation and cognitive, emotional and behavioural developments,

[1] NICE CG 28 Depression in children and young people Sept 2005
[2] BNF 66 September 2013-March 2014.